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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,036	09/28/2001	Dorrie M. Happ	50623.132	4580

7590

09/05/2003

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,036

Applicant(s)

HAPP, DORRIE M.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-11 and 14-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-7, 9-11, 14-18 and 20-24 is/are rejected.
- 7) ☒ Claim(s) 8 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 & 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Examiner acknowledges receipt of supplemental prior art filed 02/10/03; and request for continued examination under 37 CFR 1.114 and supplemental prior art filed 05/12/03. Claims 2-11 and 14-24 are pending.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 05/12/03 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 14 recites the limitation "the method" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 5 is directed to a coating composition and the claim does not recite a method of coating a medical device. For examination purposes, claim 14 is interpreted as a composition and as a composition claim, the said claim may properly then depend from claim 5.

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Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 2-7, 9-18, 20-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Harish et al. (US 2002/0122877 A1).

Harish discloses a “method of forming a coating onto an implantable device or endothelial prosthesis, such as stent” and the coating composition comprises an active ingredient (abstract) dispersed in a blended composition of polymer and solvent (page 2, paragraphs [0024] – [0026] to page 3, paragraphs [0029] and [0030]). The active ingredients are antiproliferative agents such as actinomycin, antineoplastic agents such as paclitaxel and docetaxel and antimitotic agents such as vincristine (page 3, paragraphs [0030] and [0031]). The coating composition may contain radiopaque elements or radioactive isotopes (page 1, paragraph [0012]) and an example of a radiopaque element is gold (page 4, paragraph [0034]). The coated medical implantable device or endothelial prosthesis is optionally coated with a primer layer, where the primer layer is between the surface of the device and coating composition layer that contains dispersed active ingredient; and where the primer layer is polymeric (paragraphs [0042] to [0045]). An optional topcoat, which may or may not contain active ingredient is formed onto at least a portion of the coating layer (paragraphs [0049]).

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The instant generic claim 5 is directed to a coating composition that comprises a drug-polymer composition/layer, a light/UV-protective compound contained in the coating layer and a top-coat formed over the coating drug-polymer layer. "For medical device, the coating having increased resistance to light and/or UV-radiation," does not carry patentable weight in a coating composition.

In Harish, a teaching of radiopaque element such as gold meets the limitation of the presence of light/UV-protective compound. The teachings of Harish meet the limitations of the claims.

7. Claims 8 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach a further film forming polymeric layer that is disposed on the top-coat and where the film forming layer comprises light and/or UV-protective compound on

8. The following art made of record and are equally pertinent to applicant's disclosure.

Harish et al. (US 6,503,556 B2), Hossainy et al. (US 2001/0014717 A1) and Pacetti et al. (US 2002/0123801 A1), all of which disclose medical device such as stent that is coated with polymeric composition that comprises active agents and light and/or UV-protecting compound, an optional primer composition is deposited on the surface of the device between the coating composition and the stent and an optional top-coat of barrier polymer coating is disposed on the coating composition (see entire documents).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374.

The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600

